K041050

JUN 1 5 2004

SOREDEX

510(k) Summary

Date
April 19, 2004

Submitters Information
Soredex Instrumentarium Corporation
Elimaenkatu 22
00510 Helsinki
Finland
Phone: +358 10 394820
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Contact: Kai Lanér

Trade Name
Digora Optime (or Ontime)

Common Name
Imaging plate reader

Classification
Solid state x-ray imager

Predicate Device
Digora
510(k): K934949

Product Description
A digital radiography system for intra oral imaging plates located in disposable bags. The system may be used with all x-ray equipment which is designed for intra oral radiography. The image is recorded on reusable imaging plate which substitutes for conventional x-ray film. The x-ray energy absorbed in the imaging plate remains stored as a latent image. When fed to the device the stored energy is released as an optical emission proportional to the stored energy when the imaging plate is stimulated pixel by pixel by a scanning laser. An optical system collects the emission for photo electronic system, which converts the emission to digital electronic signals. These signals are processed in a computer system which formats and stores the signals.

Further image processing, display and achieving are carried out with an auxiliary software (such as Digora for Windows K983267), a PC.

Intended Use
The Digora Optime imaging system is indicated for capturing, digitization and processing of intra oral x-ray images stored in imaging plate recording media.

Technological Characteristics
The subject device represents capability of reading imaging plates, which in size correspond to the number 0,1,2 and 3 intra oral films.
The image pixel bit depth in the predicate device is 8 bits and correspondingly in the subject device 14 bits.

Performance data
A comparison between Digora Optime and Digora was made to evaluate the need of dose to produce equal pixel value of a known object and the spatial resolution. The dose required to for a certain pixel-value was equivalent of that required for Digora. Spatial resolution for Digora is 8 lp/mm, and 10 lp/mm for Digora Optime.

Conclusion
Digora Optime has found to have substantially equivalent physical performance as the predicate device Digora.
Digora Optime has also be shown to be able to provide images of equivalent or slightly better diagnostic capability to the predicate device Digora.
Digora Optime is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 5 2004

Mr. Kai Lanér
Director
Soredex Instrumentarium Corporation
Elimaenkatu 22 B
Helsinki
FINLAND

Re: K041050
Trade/Device Name: Digora Optime
(or Digora Ontime)
Regulation Number: 21 CFR 892.1630
Regulation Name: Electrostatic x-ray
imaging system
Regulatory Class: II
Product Code: 90 MQB
Dated: April 19, 2004
Received: April 22, 2004

Dear Mr. Lanér:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) NUMBER : K041050

DEVICE NAME : DIGORA OPTIME (or DIGORA ONTIME)

INDICATIONS FOR USE :

The Digora Optime imaging system is indicated for capturing, digitization and processing of intra oral x-ray images stored in imaging plate recording media.

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041050